

EXHIBIT R

ORIGINAL ARTICLE

Long-term efficacy of Burch colposuspension: a 14-year follow-up study

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Background. The aim of this study is to investigate the long-term efficacy of the Burch colposuspension and to analyze the risk factors for an unsuccessful outcome at the long-term follow-up of more than 10 years.

Methods. Data from patient files of 190 women on whom surgery was performed with Burch colposuspension during 1980–1988 and answers from a postal questionnaire performed median 14 years after the Burch colposuspension concerning the lower urinary tract function were retrieved retrospectively.

Results. Subjectively significant urinary incontinence was experienced by 56% of the responders. Only 19% reported no incontinence episodes. Among the significant urinary incontinent women, symptoms of stress incontinence occurred in 26%, urge incontinence in 17%, and mixed incontinence in 42%. In 15%, the symptom of incontinence was atypical and could not be categorized. Feeling of incomplete bladder emptying post-operatively and pre-operative obesity was associated with the long-term outcome of Burch colposuspension (odds ratio (OR) = 2.33; 95% confidence interval (95% CI) = 1.20–4.54 and OR = 2.52; 95% CI = 1.10–5.77, respectively). Age, obesity at the long-term follow-up or having had surgery for fecal incontinence, genital prolapse, or hysterectomy were not significantly associated with the outcome of the Burch colposuspension.

Conclusions. The subjective cure rate decreases with time after Burch colposuspension. Lower urinary tract symptoms are very common at the long-term after Burch colposuspension with more than three-fourth experiencing these. Feeling of incomplete bladder emptying post-operatively and pre-operative obesity seem to be long-term risk factors for an adverse outcome. A standard definition for follow-up periods is suggested.

Key words: Burch colposuspension; cure rate; long-term follow-up; risk factor; urinary incontinence

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The mean age of women who undergo surgery for stress urinary incontinence (SUI) is about 50 years (1–3). Because the expected lifetime of women is more than 75 years in most western countries, these women may be assumed to live more than 25 years after the surgery. The first surgery is the most successful one and recurrent

surgeries show lower cure rates (3,4). This emphasizes the importance of long-term durability of the first surgical procedure.

Burch colposuspension is considered as one of the most effective surgeries for the treatment for genuine SUI (5,6). The method is, however, encumbered with a significant post-operative morbidity, such as an increased occurrence of voiding difficulties and genital prolapse (3,7–10). The long-term result concerning continence even seems to decrease with time (11–13). Thus, possible risk factors for an adverse outcome may change with time.

Abbreviations:

BMI: body mass index; BSO: bilateral salpingo-oophorectomy; DIS: detrusor instability score; SUI: stress urinary incontinence; UTI: urinary tract infection.

The aim of the present study is to investigate the long-term efficacy of the Burch colposuspension and to analyze the risk factors for an unsuccessful outcome at the long-term follow-up of more than 10 years.

Patients and methods

The 243 patients with SUI operated upon with the Burch colposuspension at our department during 1980–1988 have previously been described in detail (3). Seven had died at the 6-year follow-up and four did not answer the questionnaire in 1990. Of the remaining 232 women, 12 were deceased in 1998, thus 220 were accessible for the present study. The patient files were retrieved and information concerning pre-operative length and weight of the patient, per-operative bleeding volume, and clinical competence of the surgeon (senior consultant, consultant, senior registrar, registrar) was registered.

In November 1998, a postal questionnaire was sent to all patients alive. The postal questionnaire consisted of 66 questions concerning the symptoms of pelvic floor dysfunction, pregnancies, childbirths, gynecologic surgery, general health and demographics. The questions were selected from published questionnaires concerning the urinary and bowel functions (14,15). Twenty-six questions concerned the bowel function (15). The result of these questions is outside the scope of this study; thus, it has not been reported in this study. Nineteen questions were about the lower urinary tract function (14). Ten of these questions were modified from the Detrusor Instability Score (DIS) developed by Kauppila et al. (16) and were only answered by the women who stated that they then had urinary incontinence.

The incontinence was categorized according to the answers of the questions concerning the occurrence of incontinence at physical activity/exertion or at urge as stress incontinence or urge incontinence. Mixed incontinence was defined as incontinence when the patient exhibited symptoms of both stress and urge incontinence.

The options for answers of the questions in the questionnaire were operationalized to a limited number of box-alternatives or to specification of a number. The question concerning the occurrence of urinary incontinence was answered giving the frequency of incontinence episodes in: never; a few times per year; a few times monthly; a few times weekly, or daily episodes of incontinence. The type of daily working activity was stated on a three-grade scale as: light, quiet, mostly sitting work; much physical activity, but no physical heavy lifting; and heavy work with daily heavy lifting.

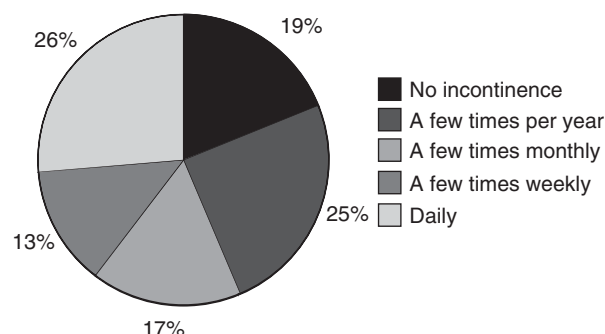


Fig. 1. Distribution of the occurrence of urinary incontinence median 14 years after Burch colposuspension in 190 women.

The occurrence of incontinence was dichotomized and leakage that occurred with a frequency of monthly or more often was considered as significant incontinence.

The non-responders received a reminding letter with a questionnaire within 3 weeks after the first letter. No further contact was established if the person did not respond after that letter.

The study was approved by the Ethical Research Committee of the Medical Faculty of Linköping University, Sweden.

Statistics

The data have been presented as numbers and frequencies or median and range. The results were analyzed statistically by means of non-parametrical statistics. Mann–Whitney *U*-test and Kruskal–Wallis test were used, when appropriate. In the analyses of associations between urinary incontinent and continent women, the Mantel–Haenszel technique for the determination of odds ratio (OR) and 95% confidence interval (CI) was used. A *P*-value of <0.05 was considered significant.

Results

The response rate of the postal questionnaire was 87% (192/220). The one hundred ninety women who answered the question concerning the occurrence of urinary incontinence made up the study group. The median follow-up period was 14.0 years (range: 10–18).

Subjectively significant urinary incontinence was observed in 56% (107/190) median 14 years (range: 10–18) after the Burch colposuspension. The frequency distribution of the occurrence of urinary incontinence has been demonstrated in Fig. 1. In the group with significant urinary incontinence, the symptoms of stress incontinence, urge incontinence, or mixed incontinence were found in 26, 17, and 42%, respectively. In 15%, the symptoms were atypical and the urinary incontinence could not be categorized as stress, urge, or mixed incontinence.

At least one of the symptoms of voiding problems – difficulty in starting voiding, straining at voiding, or feeling of incomplete emptying of the bladder – occurred in 36% (69/190). Difficulties in starting voiding were reported in 12%, straining at voiding in 11%, and difficulties in emptying the urinary bladder in 30%. In the incontinent women, recurrent lower urinary tract infections (UTI) three times or more per year occurred in 10%. Only those who reported any urinary incontinence answered the questions concerning the DIS. Of the 154 with any urinary incontinence, 109 completed these questions. The median DIS was 9 (range: 3–16) among those who were categorized as having significant urinary incontinence, and also 9 (range: 5–13) among those with subjectively non-significant urinary incontinence.

The difference in DIS was not statistically significant.

According to the body mass index (BMI), 19% were classified as obese (BMI ≥ 30 kg/m²) at the time of the surgery and 35% had overweight (BMI ≥ 25 and < 30). At the follow-up, 21% were classified as obese and 42% as having overweight.

Twenty surgeons performed the surgeries. Six of the surgeons performed 70% of the surgeries. The senior consultants performed surgery on 13% of the patients; the consultants performed surgery on 12%; the senior registrars performed surgery on 69%, and the registrars performed surgery on 6%. No significant difference was found in cure rate between the various categories of surgeons.

The median per-operative bleeding was 200 ml (range: 50–2400). The consultants and registrars had significantly larger per-operative bleedings, compared to the senior consultants and senior registrars (median: 300, 275, 150, and 200 ml, respectively; Kruskal–Wallis test; $P = 0.018$). Ten of the patients had per-operative bleeding of ≥ 1000 ml. There were no significant differences in per-operative bleeding volume or the number of patients with bleeding of ≥ 1000 ml between the continent and the incontinent at the long-term follow-up.

Concomitant gynecologic surgery at the Burch colposuspension was performed in 19 patients (10%); total abdominal hysterectomy with or without salpingo-oophorectomy (BSO) was performed in 10 patients (5.2%); subtotal abdominal hysterectomy with or without BSO in three patients (1.5%); ovarian resection in two patients (1%); closure of the pouch of Douglas ad modum Moschowitz in one patient (0.5%); posterior colporrhaphy in three patients (1.5%). At the time of the follow-up, 37% in all had had surgery

for genital prolapse, 29% had undergone hysterectomy, 12% had had BSO, and fecal incontinence surgery had been performed in 3%.

The associations between possible risk factors and the occurrence of significant urinary incontinence have been shown in Tables I–III. The follow-up period was similar – 14.0 years (range: 10–18) for the significant incontinent women and the continent women.

Pre-operative obesity (BMI ≥ 30) was strongly associated with the outcome of the surgery at the long-term follow-up. At the 6-year follow-up, this association was not significant (OR = 1.77; 95% CI = 0.84–3.75). The older age groups (≥ 60 years at the time of the surgery) demonstrated lower cure rates, but not significantly. Hysterectomy, surgery for genital prolapse, or fecal incontinence did not seem to be associated with the long-term efficacy concerning urinary continence. The associations between voiding problems and urinary incontinence seemed to withstand even at the long-term follow-up. The occurrence of at least one of the three symptoms of voiding dysfunction was significantly more often seen in the group with subjectively significant urinary incontinence than that among the non-significant incontinent women. Of the three symptoms of voiding problems investigated, only difficulty in emptying the urinary bladder was statistically and significantly more common in the incontinent group. Comparing the occurrence of at least one of the voiding dysfunction symptoms between those with urinary leakage of any frequency and those who were completely continent after the colposuspension at the long-term follow-up showed a stronger association with an OR of 13.1; 95% CI = 3.04–56.4. Each of the three symptoms did show significant associations

Table I. Associations between the demographic and obstetric data and the occurrence of significant urinary incontinence median 14 years after Burch colposuspension

	Urinary incontinent women <i>n</i> = 107 (%)	Urinary continent women <i>n</i> = 83 (%)	<i>P</i> -value or OR (95% CI)
Age at surgery (years)	49.0 (28.2–75.1)	48.0 (30.8–71.7)	Not significant
Age ≥ 60 years at surgery	19 (18)	9 (11)	1.78 (0.76–4.16)
Estrogen treatment at present*	68 (63)	42 (51)	1.70 (0.95–3.05)
Heavy work load	45 (43)	31 (35)	1.38 (0.77–2.47)
Body mass index (BMI) at surgery (kg/m ²)	25.8 (18.5–36.6)	24.5 (19.5–38.3)	Not significant
BMI of ≥ 30	25/99 (25)	9/76 (12)	2.52 (1.10–5.77)
BMI at follow-up (kg/m ²)	26.6 (19.6–38.6)	25.7 (18.8–37.2)	Not significant
BMI of ≥ 30	25/103 (24)	12/79 (15)	1.79 (0.84–3.83)
Parity	2.0 (0–8)	2.0 (0–7)	Not significant
Nulliparous	3 (2.8)	3 (3.6)	0.77 (0.15–3.91)
Mode of delivery			
Normal vaginal deliveries	93 (89)	71 (89)	1.07 (0.42–2.73)
All other modes	11 (11)	9 (11)	
Large perineal lacerations or episiotomy	13 (13)	9 (12)	1.19 (0.42–2.94)

*Estrogen treatment includes local and systemic treatment.

Table II. Associations between the clinical data and the occurrence of significant urinary incontinence median 14 years after Burch colposuspension

	Urinary incontinent women <i>n</i> = 107 (%)	Urinary continent women <i>n</i> = 83 (%)	<i>P</i> -value or OR (95% CI)
Hysterectomy at anytime	34 (32)	22 (27)	1.29 (0.68–2.44)
Before Burch colposuspension	8 (7)	6 (6)	1.26 (0.40–4.00)
Concomitant to Burch colposuspension	9 (8)	4 (5)	1.80 (0.54–6.11)
Subsequent to Burch colposuspension	17 (16)	13 (16)	1.02 (0.46–2.23)
Genital prolapse surgery at anytime	38 (36)	32 (39)	0.88 (0.48–1.59)
Before Burch colposuspension	3 (3)	4 (5)	0.57 (0.12–2.62)
Concomitant to Burch colposuspension	3 (3)	0 (0)	Not significant
Subsequent to Burch colposuspension	32 (30)	28 (34)	0.84 (0.45–1.55)
Fecal incontinence surgery	5 (4.7)	1 (1.2)	4.02 (0.46–35.1)

when comparing those with urinary incontinence of any frequency with those who were completely continent (data not shown). In all women with incontinence of any frequency, recurrent UTI occurred in 14% of the women with voiding problems and in 8% of those without voiding problems (OR = 1.78; 95% CI = 0.63–5.07).

Discussion

Follow-up studies concerning anti-incontinence surgery often consider 3–5 years as long-term (1–3). This time period is probably too small, because the recurrence rate usually increases with time (3,11–13,17). Thus, in order to disclose the risk factors, real long-term follow-up is necessary. The established risk factors at the short-term follow-up may change with time. There is no general accepted standard by the international community, i.e. the International Continence Society or the International Urogynecological Association, of what is long-term follow-up in urogynecology. This should be considered in the international urogynecologic society in order to obtain correct comparisons of the outcome of treatments. In pelvic floor reconstructive surgery, any follow-up period of less than 5 years should be noted as short-term follow-up, a follow-up period of 5–10 years as a medium-term follow-up, and a follow-up period of 10 years or more should be noted as long-term follow-up.

The present long-term follow-up study of the Burch colposuspension demonstrates a deterioration of the continence rate with time. In the pre-

viously published 6-year follow-up study (3), the subjective continence rate was 63%, compared to the 44%, 14 years after the Burch colposuspension. Alcalay et al. (11) found that the cure of incontinence following Burch colposuspension was time-dependent, with a decline for 10–12 years when a plateau was reached. The results of our study are comparable with those of other long-term studies of the Burch colposuspension (1,11,13,17).

Voiding difficulties have been reported to be a major concern after Burch colposuspension occurring in 22–32% even at the long-term (3,7,11). Compared to our 6-year follow-up study (3), the occurrence of voiding difficulties seemed to remain unchanged at the 14-year follow-up. Lose et al. (7) found approximately 40% with stranguria, i.e. a symptom of voiding dysfunction 26 months after the surgery. The present study confirms that the significant morbidity of voiding problems after Burch colposuspension persists at the long-term with 36% having the feeling of incomplete bladder emptying.

As reflected in the high DIS found in the incontinent group, a large proportion of the women with significant urinary incontinence after Burch colposuspension had the symptoms of urgency and urge incontinence (59% – urge incontinence 17% + mixed incontinence 42%), which has also been reported by other authors (7,11,13,18,19). Subjectively *de novo* urge symptoms occurred in 36%. This emphasizes the statement by Sand and co-workers that patients undergoing Burch colposuspension should understand the possibility

Table III. Associations between voiding problems and the occurrence of significant urinary incontinence median 14 years after Burch colposuspension

	Urinary incontinent women <i>n</i> = 107 (%)	Urinary continent women <i>n</i> = 83 (%)	OR (95% CI)
At least one symptom of voiding dysfunction	46/107 (43)	23/83 (28)	1.97 (1.06–3.64)
Difficulties in starting voiding	15/105 (14)	8/81 (10)	1.52 (0.61–3.79)
Straining at voiding	13/105 (12)	7/81 (9)	1.49 (0.57–3.93)
Difficulties of emptying the bladder	39/103 (38)	17/82 (21)	2.33 (1.20–4.54)

that the surgery may cause urinary incontinence because of detrusor instability even if it cures their genuine stress incontinence and that if they have both genuine stress incontinence and detrusor instability their chances for an operative cure of both conditions are low (19).

The occurrence of recurrent UTI seemed to decrease. In the 6-year follow-up, it was 16% among the patients with incontinence (3); at the 14-year follow-up, it was 10%. Lose et al. (7) found UTI in 29% of all at the follow-up mean of 26 months, whereas Alcalay et al. (11) reported recurrent UTI in 5% in their 10–20 year follow-up study.

The occurrence and the development of genital prolapse have been associated with Burch colposuspension (9,10,13). Kwon et al. recently published a study that questioned this association (20). They found that genital prolapse did not occur later on in those women who pre-operatively did not have a prolapse. The dropout rate in their study was 43% and the examination used pre-operatively and post-operatively was, however, not uniform and thus the results were uncertain. In the present study, genital prolapse surgery had been performed in 37% of the patients at the long-term follow-up. In the study by Alcalay et al., 30% had had a prolapse surgery before the colposuspension and afterward 26% had a posterior repair and 5% an enterocele repair (11). The association between the outcome of colposuspension and the occurrence of genital prolapse is unclear. We have previously reported that genital prolapse occurs significantly more often in the group of incontinent women after Burch colposuspension (9). But when it comes to genital prolapse that demands surgery this seems not to hold through. In the present study, the OR for genital prolapse surgery demonstrated a higher risk of prolapse surgery in the continent group than that in the incontinent group, although not significant.

The reports on the influence of hysterectomy on the outcome of the Burch colposuspension are conflicting. However, often the association has been made with hysterectomy performed before or concomitant to the colposuspension surgery (21,22). If pelvic floor neuropathy caused by the hysterectomy is the etiology of urinary incontinence as suggested by Parys et al. (23) and Benson and McClellan (24), it seems more appropriate to determine the outcome of the colposuspension in relation to whether a hysterectomy has been performed or not at the time of the follow-up. This has been performed in the present study. Twenty-nine percent had had a hysterectomy. No significant difference was

found in the incidence of having undergone hysterectomy between the significant urinary incontinent and continent women after Burch colposuspension at the long-term follow-up. The time of the executions of the hysterectomy in relation to the colposuspension did not seem to influence the outcome of the colposuspension either.

Controversy about the influence of the age at surgery for an adverse outcome of the Burch colposuspension exists (3,21,25,26). We found no significant difference in the outcome concerning continence in any particular age group. In our previous study (3), there was a trend for a lower cure rate for women older than 64 years at surgery. However, owing to the small number of remaining living patients from this age group, the results are not shown specifically for the age group of ≥ 65 years.

Obesity (i.e. BMI of $\geq 30 \text{ kg/m}^2$) at the time of the surgery was strongly associated with the outcome of the colposuspension at the long-term follow-up. The obese women had an increased risk of an adverse outcome of the surgery, compared to non-obese women. This is in accordance with other studies (11,27). Alcalay et al. (11), however, did only report the weight of the patient, which seems insufficient when describing obesity. On the contrary, Zivkovic et al. (28) reported no significant influence of the BMI on the outcome after Burch colposuspension, but their report was small with a low statistical power. The question is: What impact may weight reduction pre-operative have on the outcome of the colposuspension? No studies have been performed with this goal.

In the present study, BMI increased between the surgery and the follow-up in both groups. Thus, it seems that the weight increase after the surgery *per se* does not influence the outcome of the surgery.

Conclusions

This study demonstrates that the symptoms of lower urinary tract dysfunction are common at long-term follow-up, median 14 years after Burch colposuspension. Only 19% claim that they were completely continent. In 25%, the incontinence episodes occurred only a few times per year and 56% experienced significant urinary leakage monthly or more often. Symptoms of SUI occurred in 68% of those with significant leakage and urge incontinence was almost as common, occurring in 59%. The cure rate of the Burch colposuspension seemed to decline over time. Pre-operative BMI and post-operative

feeling of incomplete bladder emptying seem to be associated with the long-term symptom of urinary incontinence after the colposuspension. An international standard for definitions of follow-up is wanted and is suggested. The new minimal invasive techniques for surgical treatment for SUI seem promising concerning the cure rate as well as morbidity. However, no long-term studies (≥ 10 -year follow-up) have been published.

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